

Appl. No. 09/692,634  
Atty. Docket No. 8308  
Amdt. dated April 10, 2006  
Reply to Office Action of 12/23/05  
Customer No. 27752

## REMARKS/ARGUMENTS

### Claim Status

New claims 31-37 have been added. No additional claim fee is believed to be due. Claims 1-7 and 20-27 are pending.

Claims 8-19, and 28-30 were previously canceled without prejudice.

Claim 1 has been amended to recite a pH adjusting agent and pH of the composition. Support for the pH adjusting agent and pH of the composition on the nasal tissues is found at page 6, lines 25-33 of the specification. In Claim 2, the range of pyroglutamic acid has been amended. Support is found at page 6, lines 7-9. Claim 20 has been amended to include particular metal salts. Support for the metal salts is found at page 9, lines 5-32. No new matter has been added.

### Rejections Under 35 USC §103(a) Over Yamamoto in view of Li, et al.

Claims 1-5 and 20-25 are rejected under 35 USC §103(a) as being unpatentable over Li, J. et al. CN 1079259 (hereinafter referred to as "Li"), in view of the article entitled: Simultaneous Determination of Organic Acids in Commercial Vinegar by Photometric Chromatography (hereinafter referred to as "Yamamoto"). Applicants traverse all rejections of claims 1-5 and 20-25 to the extent that they may apply to the claims as now amended.

At the outset it is submitted that Li has been improperly applied as a reference. The Chinese filing date of Li is listed as March 29, 1999, with a publication date of November 3, 1999. The present Application claims a priority date of October 19, 1999. In the Office Action dated June 27, 2002, the Examiner states that the Applicants did not comply with one or more conditions for claiming domestic priority under 35 USC § 120 and the Examiner declared the effective priority date of the application to be October 19, 2000. The Applicants traversed this rejection in a response dated September 26, 2002.

In the subsequent Office Action dated December 17, 2002, the Examiner stated that any rejection that was not addressed in that Office Action was considered obviated in view of the Applicants' arguments and amendments. The priority claim was not again addressed in the Office Action dated December 17, 2002, and was thus presumed to have been obviated. Therefore, the priority date of the application is October 19, 1999.

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In the event the Examiner had intended to maintain the issue regarding the priority date of October 19, 1999, some response in rebuttal to the Applicants' traversal and supporting arguments is requested, so that the matter can be properly addressed by Petition or otherwise.

Inasmuch as the Applicants' un rebutted priority date of October 19, 1999, predates the publication of Li on November 3, 1999, Li is not a proper reference. Therefore, the only relevant reference applicable to the rejection is Yamamoto.

Even assuming *arguendo* that Li is a properly applied reference, a *prima facie* case of obviousness has not been established because neither Li nor Yamamoto, either alone or in combination, teaches or suggests all of the claim limitations of Claims 1-5 and 20-25. See MPEP 2143.03.

The Examiner asserts that Li teaches a nasal preparation for treating influenza or common cold containing edible vinegar. The Examiner then asserts that Yamamoto teaches that vinegar liquid contains pyroglutamic acid and a secondary acid such as succinic or acetic acid, which fall within the scope of the claimed acids. Thus, the Examiner asserts that Li's composition contains pyroglutamic acid used to treat cold or flu. The Applicants respectfully disagree.

Yamamoto teaches only a method of measuring multiple acids present in vinegars. Yamamoto teaches nothing with respect to the Applicants' claimed methods and compositions. Yamamoto does not teach or suggest methods of treating colds and flu by any method, and certainly does not teach or suggest adding pH adjusting agents to vinegar for any purpose. Therefore there is no teaching or suggestion whatsoever in Yamamoto that would lead one of ordinary skill in the art to the Applicants' invention.

Moreover, present Claim 1, as amended, and new Claim 34 recite the addition of a pH adjusting agent, and a pH of the composition when applied to nasal cavity tissues of from about 3.5 to about 5.5. Neither Li nor Yamamoto teaches or suggests adding a pH adjusting agent to vinegar or vinegar-containing compositions. In addition, neither Li nor Yamamoto teaches or suggests anything regarding the pH of the composition, particularly as present on the nasal tissues. The Applicants' composition has a pH on the nasal tissues of from about 3.5 to about 5.5. The unadjusted pH of vinegars would be expected to be considerably lower, as evidenced by the pH of 1.9 given for the Japanese apricot vinegar of the previously cited Kawashima document. See Table 1 of Kawashima.

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Therefore, a composition having the Applicants' recited pH adjusting agent and pH of the composition on nasal cavity tissue is not taught or suggested by either a vinegar solution or a paste or ointment containing an edible vinegar. Furthermore, Li teaches a nasal ointment or cavity paste, not a liquid solution that is sprayed into the nasal turbinates.

The Examiner also asserts that pKa value is an inherent property of pyroglutamic acid and that the pyroglutamic acid of edible vinegar would have possessed a pKa value within the Applicants' claimed ranges. Therefore, the Examiner asserts that it would have been obvious to use edible vinegars nasally for treatment of cold or flu. The Applicants point out that the present claims do not recite a pKa value with respect to pyroglutamic acid. Rather, the pKa value recited is the pKa value for the additional organic acid. See page 6, lines 10-17 of the specification. Thus, the combination of Li and Yamamoto would not lead one of skill in the art to the Applicants' invention. Therefore, Claims 1 and 34 and the claims that depend therefrom are not obvious in view of either Li or Yamamoto, either alone or in combination.

With particular regard to Claims 2, 32, and 34, each of these claims recites an amount of pyroglutamic acid from about 1% to about 20% by weight of the composition. The amount of pyroglutamic acid in vinegars, as evidenced by Yamamoto, is well below the Applicants' claimed range. See Table II of Yamamoto. Neither Li nor Yamamoto teach or suggest any amount of pyroglutamic acid beyond that normally present in vinegars. Particularly, neither Li nor Yamamoto teaches or suggests an amount of pyroglutamic acid from about 1% to about 20% by weight of the composition. Thus, the combination of Li and Yamamoto would not lead one of skill in the art to this embodiment of the Applicants' invention. Therefore, Claims 2, 32, and 34 are not obvious in view of either Li or Yamamoto, either alone or in combination.

Finally, with particular regard to claims 20-25 and new claims 36 and 35, each of these claims recites metal salts. The Examiner rejects claims 20-25 based on Li and Yamamoto. However, the Examiner offers no specific basis for the rejection of the claims drawn to metal salts. Neither Li nor Yamamoto teaches or suggests anything with respect to metal salts. Therefore Claims 20-25, 36 and 37 would not have been obvious in view of either Li or Yamamoto, either alone or in combination.

In light of the foregoing, the Applicants respectfully request withdrawal of the rejections.

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Rejection Under 35 USC §103(a) Over Li et al. in view of Yamamoto and further in view of Szentmiklosi et al.

Claims 6-7 and 26-27 are rejected under 35 USC §103(a) as being unpatentable over Li in view of Yamamoto as applied to claims 1-5 and 20-25 and further in view of Szentmiklosi et al., US Patent 5,244,880 (hereinafter referred to as "Szentmiklosi").

The Examiner asserts that Szentmiklosi discloses that suitable carrier systems for topical compositions can comprise carbohydrate polymers. In addition, the Examiner asserts that it would have been obvious to prepare a solution of vinegar, that contains pyroglutamic acid, and add a mucoadhesive polymer.

The Applicants respectfully traverse the rejections. As argued above, Li is not a proper reference. Further, the combination of Yamamoto and Szentmiklosi would not have led one of ordinary skill in the art to the Applicants' methods or compositions.

As argued above, neither Li nor Yamamoto, either alone or in combination, establishes a *prima facie* case of obviousness. Even beyond that, the Examiner is correct that neither Li nor Yamamoto teach or suggest anything with respect to mucoadhesive carbohydrate polymers.

There is no motivation in Yamamoto to combine vinegar with anything for any reason. Yamamoto simply developed a method for analyzing multiple components of vinegar simultaneously via HPLC. Simply because Li discloses a paste that can be applied to the nose and contains edible vinegar, and Szentmiklosi discloses mucoadhesive polymers, that, alone, would not have led one of ordinary skill in the art to combine such polymers with vinegar and to introduce such hypothetical compositions into the nasal turbinates for any reason whatsoever.

There must be some motivation or suggestion, in the cited documents, to combine the documents in order for an obviousness rejection to stand. See MPEP 2143.03. In this case there is no such motivation. Even if Li were a proper reference, and even if a vinegar solution or paste were prepared and a mucoadhesive polymer were added to a vinegar solution or paste, as the Examiner suggests in the Official Action at page 5, the last sentence of the first paragraph, the Applicants' compositions and methods would still not result.

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In addition, again, even if Li were available as a reference, it still does not suggest adjusting the pH of vinegar. As noted above, in view of the previously cited Kawashima document, the pH of a vinegar solution would be expected to be well below the Applicants' range. The cited documents provide no teaching or suggestion with respect to a pH adjusting agent, a pH that would be suitable for a composition that is sprayed into one's nose, or how to achieve such a pH. Neither Li nor Yamamoto teach or suggest any way to achieve a composition having a pH of about 3.5 to about 5.5 on the nasal tissues. Therefore, combining teaching regarding mucoadhesive polymers to teaching regarding measuring acids in vinegars would not lead one of skill in the art to the Applicants' invention.

Thus, none of the cited documents, alone or in combination, teaches or suggests the Applicants compositions or methods. Therefore, the Applicants respectfully request withdrawal of the rejections.

#### Conclusion

In light of the above amendments and remarks, it is requested that the Examiner reconsider and withdraw the rejections under 35 USC §103(a). Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention from the applied references. In view of the foregoing, reconsideration of this application and allowance of Claims 1-5, 20-25, and 31-38 are respectfully requested.

Respectfully submitted,

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